SETTLEMENT AGREEMENT BETWEEN MISSOURI BOARD OF PHARMACY AND MARTIN HINTERLONG, d/b/a THE MEDICINE SHOPPE, #005448

Comes now Martin Hinterlong, d/b/a the Medicine Shoppe #005448 ("Licensee or Respondent") and the Missouri Board of Pharmacy ("Board") and enter into this settlement agreement for the purpose of resolving the question of whether Licensee's permit to operate a pharmacy will be subject to additional discipline.

Pursuant to the terms of § 324.042, Cum. Supp. 2008, the parties hereto waive the right to a hearing by the Missouri Board of Pharmacy regarding whether there is cause to impose additional discipline on Licensee's permit.

Licensee acknowledges that he understands the various rights and privileges afforded him by law, including the right to a hearing of the charges against him; the right to appear and be represented by legal counsel; the right to have all charges against him proven upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against him; the right to present evidence on his own behalf at the hearing; the right to a decision upon the record concerning the charges pending against him and, subsequently, the right to recover attorney's fees incurred in defending this action against his permit. Being aware of these rights provided him by operation of law, Licensee knowingly and voluntarily waives each and every one of these rights and freely enters into this settlement agreement and agrees to abide by the terms of this document, as they pertain to him.

Licensee acknowledges that he has received a copy of the probation violation complaint and other documents relied upon by the Board in determining there was cause to impose additional discipline on his permit, along with citations to the terms and conditions and the law and/or regulations the Board believes was violated.

For the purpose of settling this dispute, Licensee stipulates that the factual allegations contained in this settlement agreement are true and stipulates with the Board that Licensee's permit, numbered 005448 is subject to additional disciplinary action by the Board in accordance with the provisions of Chapter 324, as amended and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS AND CONCLUSIONS OF LAW

- 1. The Missouri Pharmacy Board ("Board") is an agency of the State of Missouri created and established pursuant to Section 338.140, RSMo¹, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
- 2. Jurisdiction and venue are proper pursuant to Sections 338.055.3 and 621.045, as amended.
- 3. Martin J. Hinterlong ("Hinterlong") d/b/a the Medicine Shoppe holds pharmacy permit number 005448 to operate a Missouri pharmacy, Class A and C (the "Pharmacy License") at 920 M St. Clair Plaza Drive, St. Clair, Missouri (the "Pharmacy"). The Pharmacy License was current and active at all times relevant herein.
- 4. Hinterlong is the permit holder and the pharmacist in charge ("PIC") at the Medicine Shoppe Pharmacy.
- 5. At all times relevant herein, the Pharmacy provided prescription services to long term care facilities pursuant to 20 CSR 2220-2.140 and prescription compounding services under the provisions of 20 CSR 2220-2.400.
- 6. Hinterlong and the Board entered into a "Settlement Agreement Between State Board of Pharmacy and Martin J. Hinterlong d/b/a Medicine Shoppe" on July 31, 2006 that

All statutory references are to the Revised Statutes of Missouri (2000), as supplemented, unless otherwise indicated.

placed the Pharmacy License on probation from August 15, 2006 through August 14, 2011 ("Board Agreement.").

- 7. Paragraph C on page 8 of the Board Agreement provides that "Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States."
 - 8. Hinterlong signed for and received a fully executed copy of the Board Agreement.
- 9. On July 18, 2006, the Pharmacy, by and through Hinterlong, entered into a Settlement Agreement with the Missouri Department of Health and Senior Services' Bureau of Narcotics and Dangerous Drugs ("BNDD Agreement").
- 10. The BNDD Agreement required the Pharmacy have a practice monitor and regular audits of the Pharmacy's controlled substances.
- 11. Jim Cordes serves as the practice monitor for the Pharmacy under the BNDD Agreement.
- 12. At all times relevant herein, the Pharmacy provided prescription services to long term care facilities pursuant to 20 CSR 2220-2.140 and prescription compounding services under the provisions of 20 CSR 2220-2.400.
- 13. Board regulation 20 CSR 2220-2.090 sets forth a PIC's responsibilities, it states in pertinent part:

* * *

- (2) The responsibilities of a pharmacist-in-charge, at a minimum, will include:
- (E) Assurance that all procedures of the pharmacy in the handling, dispensing and recordkeeping of

controlled substances are in compliance with state and federal laws:

* * *

- (V) No outdated drugs are dispensed or maintained within the active inventory of the pharmacy, including prescription and related nonprescription items;
- (W) Assure full compliance with all state and federal drug laws and rules;
- 14. On October 10, 2007 the Board's inspector conducted an inspection and audit of the Pharmacy (the "October Inspection and Audit").
- 15. The October Inspection and Audit identified inaccurate record keeping for Alprazolam 0.5 mg., Alprazolam 1.0 mg. and Hydrocodone/APAP 10-650.
 - 16. During the October Inspection and Audit the Board's Inspector also observed:
 - Phannacy personnel not wearing gloves when repackaging cards for LTCF's;
 - B. There were no written policies and procedures for services provided to residents of Long Term Care Facilities as required by 20 CSR 2220-2.140(2)(A);
 - C. There were 89 expired drugs (44 of which were contained in four boxes) in the active inventory in violation of the Food Drug and Cosmetic Act, section 501 [351] (a) (a) (B);
 - D. Active ingredients in compounded prescriptions were not listed on all containers provided to customers as required by 20 CSR 2220-2.400 (7)(F) as evidenced by missing information for two prescriptions;
 - E. There was not a certificate of analysis on file for a non USP/NF bulk drug (camphor) used in compounding as required by 20 CSR 2220-2.400(8)(A)2; and
 - F. The BNDD/DEA annual inventory of controlled substances did not list the time taken or contain a header with the DEA number of the store and the pharmacy's address.

- The Pharmacy dispensed controlled substances based upon technically incomplete 17. prescriptions. The prescriptions were missing patient addresses or physician DEA numbers.
- Paragraph 2, Section E on page 11 of the Board Agreement provides that 18. "Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of the disciplinary Order/Agreement."
- The Pharmacy's conduct is in violation of the terms and conditions of the Board 19. Agreement, thus entitling Petitioner to impose further discipline.

CONCLUSIONS OF LAW

- The Pharmacy is in violation of the provisions of Chapters 338, RSMo, and thus, 20. constitutes a violation of the conditions of probation as set forth in the Board Agreement.
- 21. Section 338.055, RSMo Cum Supp. 2007, sets forth cause to discipline and states, in relevant portion:
 - The board may cause a complaint to be filed with the 2. administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

Incompetence, misconduct, gross negligence, fraud, (5)misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

4 - 1 - 1 - 1 - 1 - 1

* * *

22. Cause exists for Petitioner to take disciplinary action against the Pharmacy's permit under § 338.055.2(5), RSMo for incompetency in that Pharmacy's actions as described in this Settlement Agreement demonstrate a lack of disposition to use an otherwise sufficient professional ability.

23. There is cause to impose additional discipline on the Pharmacy Permit held by Hinterlong pursuant to Sections 338.055.2(5), RSMo, and for violations of the Board Agreement, pursuant to sections C and E on page 11.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of § 324.042, as amended.

Licensee's permit to operate a pharmacy in the State of Missouri, Permit No. 005448 is placed on PROBATION for a period of FIVE (5) years, ("disciplinary period") as of the effective date of this Agreement. The terms of discipline shall be as follows:

I. GENERAL REQUIREMENTS

- A. Licensee shall keep the Board apprised of licensed pharmacists employed by Respondent and the individuals' current home and work addresses and telephone numbers.
- B. Licensee shall pay all required fees for permitting to the Board and shall renew its permit prior to October 31 of each permitting year.
- C. Licensee shall comply with all provisions of Chapter 338, Chapter 195; all applicable federal and state drug laws, rules, and regulations; and all federal and state criminal laws. "State" here includes the state of Missouri and all other states and territories of the United States.
- D. Respondent shall not serve as an intern training facility for interns.
- E. The Permit Holder shall make himself available for personal interviews to be conducted by a member of the Board or Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Permit holder will be notified and given sufficient time to arrange these meetings.

- F. If, after disciplinary sanctions have been imposed, Respondent ceases to keep his Missouri permit current such periods shall not be deemed or taken as any part of the time of discipline so imposed.
- G. Licensee shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months, beginning six (6) months after this agreement becomes effective, stating truthfully whether or not Licensee has complied with all terms and conditions of his disciplinary order.
- H. If Licensee leaves the state of Missouri for more than 30 consecutive days, such periods shall not be included as part of the time of discipline so imposed.
- I. Respondent shall conduct an Initial Inventory at this pharmacy on all schedule controlled substances. The initial inventory shall be immediately available to a member of the board or the Board of Pharmacy staff.
- J. Respondent shall select an independent consultant for the purpose of reviewing and insuring all compliance measures are carried out in accordance with all applicable laws and regulations. Respondent shall submit document and credentials of his chosen consultant to the Board office for approval prior to the beginning date of probation. Said consultant shall submit a written plan to the Board office outlining what procedures or changes in operation will be implemented and on what time table is proposed for completion. The consultant shall then provide ongoing reports to the board office attesting to the pharmacy's compliance or noting deficiencies for each visit. The visits and initial report shall be provided within thirty (30) days of the beginning of probation. Visits to the pharmacy to assess compliance will be completed at a minimum of a six (6) month cycle and reports to the Board office will be provided once every six (6) months throughout the disciplinary period. The consultant shall be hired at Respondent's expense. Jim Cordes has been approved by the Board to serve as Respondent's consultant.
- K. The consultant shall reconcile inventories of controlled substances on a quarterly basis.
- 1. Licensee's failure to comply with any condition of discipline set forth herein constitutes a violation of this Settlement Agreement.

- 2. The parties understand that the Board of Pharmacy will maintain this Settlement Agreement as an open and public record of the Board as provided in Chapters 324, 338, 610, and 620. Cum. Supp. 2008.
- 3. Upon the expiration of said discipline, Licensee's permit to operate a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Licensee has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Licensee.
- 4. If the Board determines that Licensee has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this disciplinary order in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.
- 5. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without adequate notice to Licensee and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

- 6. The terms of this Settlement Agreement are contractual, legally enforceable, and binding, not merely recital. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.
- 7. Licensec, together with his heirs and assigns, and his attorney(s), do hereby waive, release, acquit, and forever discharge the Board, its respective members and any of its employees, agents, or attorneys, including any former Board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to § 536.087, RSMo, or any claim arising under 42 U.S.C. § 1983, which may be based upon, arise out of, or relate to any of the matters raised in this case, its settlement, or from the negotiation or execution of its settlement. Licensee acknowledges that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.
 - 8. This Agreement shall be effective on November 5, 2008.

LICENSEE

MARTIN HINTERLONG for

Medicine Shoppe Pharmacy,

Permit #005448

BOARD

THOMAS GLENSKI, R.PH.

Chief Inspector State Board of Pharmacy

Date

Robert L. Hess II #52548
Harvey M. Tettlebaum #20005
Husch Blackwell Sanders LLP
235 East High Street, Suite 200
Jefferson City, MO 65101
Telephone (573) 635-9118
Facsimile (573) 634-7854
robert.hess@huschblackwell.com
harvey.tettlebaum@huschblackwell.com

ATTORNEYS FOR RESPONDENT

Date

Loretta Schouten #52290

CPA

7970 S. Tomlin Hill Road Columbia, MO 65201 Telephone (573) 875-7169 Facsimile (573) 875-5603 llschouten@yahoo.com

ATTORNEY FOR PETITIONER